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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,119	10/04/2004	Linda Diehl	470-045183	4799

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
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09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,119	DIEHL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/11/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/30/2008 has been entered.

Applicant's amendment, filed on 07/30/2008, has been entered.

Claims 13-25 are pending.

Applicant's election with traverse of the species (A) treating a tumor in the Election With Traverse, filed 06/08/2007, has been acknowledged.

Claims 13-25 are under consideration as they read on the elected invention of species (A) tumor (and not infectious agent) in the instant application.

Claims 1-12 and 26 have been canceled previously.

2. This Action will be in response to applicant's amendment, filed 07/30/2008.

The rejections of record can be found in the previous Office Actions, mailed 09/10/2007 and 04/30/2008.

3. Priority Issues.

As indicated previously, the following of record is reiterated for convenience.
The filing date of the instant claims is deemed to be the filing date of PCT/NL03/00254, filed 04/04/2003.
Priority applications USSN 10/115,620, filed 04/04/2002 and USSN 09/316,935, filed 05/22/1999 does not support all of the current claim limitations of the instant application.

With applicant's amendment, it is noted that applicant has amended page 1 of the instant specification with respect to the priority of the instant application as follows.

Cross Reference
This application claims priority to International Application No. PCT/NL03/00254 (published as WO 03/084999), filed April 4, 2003, the contents of which are herein incorporated by reference.

The examiner acknowledges the current priority of the instant claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and Was published under Article 21(2) of such treaty in the English language.

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13-21 and 25 stand rejected under 35 U.S.C. § 102(e) as being anticipated Siegall et al. (US 2004/0235074 A1) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 07/30/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Applicants respectfully traverse the rejection. To support a rejection under Section 102, an Examiner must show that each and every element recited in the claimed invention is taught by a single reference. MPEP §2131. As admitted in the Office Action, Siegall does not expressly teach tumor-specific antigens.

As previously stated, Siegall shows that the use of a specific anti-CD40 antibody seems to induce B cell proliferation in vitro in peripheral B cells expressing CD40 (example 7.2.2). However, this example only shows that this specific antibody is able to stimulate B cells in vitro.

Siegall further shows that growth reduction of a human tumor is induced in a SCID mouse model using the same human anti-CD40 antibody (example 8). One having ordinary skill in the art is aware that an SCID mouse does not have any T and B cells. Since the anti-CD40 antibody used is a human antibody, it can only induce a growth reduction of the tumor by binding a human CD40 molecule expressed on the tumor itself. Therefore, this experiment shown in Siegall does not demonstrate any in vivo activation of T or B cells to exert an anti-tumor effect. Accordingly, Siegall fails to disclose that a systemic T cell immunity can be induced in vivo by an anti-CD40 antibody to exert an anti-tumor, let alone an anti-infectious effect.

The Examiner contends that Applicants' arguments focus only on the induction of B-cell proliferation and treatment in an SCID mouse while ignoring the teachings of Siegall in regards to the treatment of cancer and immune disorders.

Although Siegall may broadly suggest the use of anti-CD40 for treating cancer, a person of skill in the art would not consider Siegall an enabling disclosure for the subject matter of the present invention (i.e., the use of agonistic anti-CD40 antibodies for cancer treatment). The experimental data presented by Siegall, as described above, shows an absence of in vivo activation of T or B cells. As stated by the Examiner in the Office Action dated September 10, 2007, Siegall does not teach tumor-specific antigens. A person of ordinary skill in the art, by merely reading a table containing a list of malignancies and disorders, would be unable to make and/or use Applicants' present invention, specifically, the "induction of systemic T cell immunity against an antigen of the tumor or infectious agent" by the administration of the antibody, as required by independent claim 13. Siegall therefore does not disclose each and every element of the present claims.

For these reasons, Applicants respectfully request that this rejection be withdrawn.

The arguments of counsel cannot take the place of evidence in the record.
See In re Schulze, 145 USPQ 716, 718 (CCPA 1965) and Meitzner v. Mindick, 193 USPQ 17, 22 (CCPA 1977).

As pointed out previously, in contrast to applicant's assertions focusing on the induction of B cell proliferation and treatment in a SCID mouse model,
applicant ignores the clear teachings of Siegall et al. of treating cancer and immune disorders as well as activating/augmenting the immune response of a patient with agonistic anti-CD40 antibodies (e.g., see entire document, including Therapeutic Uses, Effective Doses, Formulations on pages 12-14 and Claims).

Also as pointed out previously, in contrast to applicant's focus on the Examples, Siegall et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1) as pointed out previously.

Also, note that B cells as well as dendritic cells, which express CD40, are antigen-presenting cells, which, in turn, would stimulate systemic immunity, including T cell immunity, when stimulated with agonistic anti-CD40 antibodies.

Also as pointed out previously, as pointed out previously, Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant has not distinguished the prior art administration of an agonistic anti-CD40 antibodies that can activate/augment the immune response in the treatment of cancer from the claimed methods.

Applicant is reminded that the claimed method "does not comprise immunization with an antigen or the tumor" (e.g., see independent claim 13).

In contrast to applicant's assertions, treating tumors via "tumor-specific antigens" would be inherent in the prior art administration of an agonistic anti-CD40 antibodies that can activate / augment the immune response in the treatment of cancer, which includes the activation / augmentation of antigen-presenting cells as well including the teaching of the Malignancies set forth in Table 1 on pages 12-13.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have described a beneficial effect in another manner (e.g., induction of systemic T cell immunity) from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Again, the following is reiterated for applicant's convenience.

Siegall et al. teach methods of using agonistic anti-CD40 antibodies, which enhance CD40L-mediated interactions, including chimeric and humanized, including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Section 5.6 mAb S2C6 Antibody Derivatives in paragraphs [0081] – [0091]) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention and Section 5.9 Therapeutic Uses, Section 5.9.1 Effective Dose and Section 5.9.2 Formulations on pages 12-14 and Claims). Here in Section 5.9.2 Formulations, modes of administration via injection and oral administration.

Siegall et al. teach that CD40;CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1).

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

Although the reference does not teach tumor-specific antigens per se, given the Malignancies set forth in Table 1 on pages 12-13, tumor-specific antigens would be inherent to the described tumors.

Although the reference is silent about the induction of "systemic T cell immunity against an antigen of the tumor", "wherein the treatment does not comprise immunization with an antigen of the tumor", "tumor-specific antigen" per se,
it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991).
Also, see M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have described a beneficial effect in another manner (e.g., induction of systemic T cell immunity) from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant's arguments have not been found persuasive.

7. Claims 13-21 and 25are rejected under 35 U.S.C. § 102(e) as being anticipated Siegall et al. (U.S. Patent No. 6,843,989) (see entire document) essentially for the reasons of record and herein as it applies to Siegall et al. (US 2004/0235074 A1).

Given applicant's arguments concerning the enabling disclosure of Siegall et al., Siegall et al. (U.S. Patent No. 6,843,989) has been added in a New Grounds of Rejection.

Applicant is reminded that U.S. patents are presumed valid by U.S. courts unless proven otherwise. See 35 U.S.C. 282.

Siegall et al. teach methods of using agonistic anti-CD40 antibodies, which enhance CD40L-mediated interactions, including chimeric and humanized, including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Section 5.6 mAb S2C6 Antibody Derivatives on columns 14-16) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention and Section 5.9 Therapeutic Uses, Section 5.9.1 Effective Dose and Section 5.9.2 Formulations on columns 21-26 and Claims). Here in Section 5.9.2 Formulations, modes of administration via injection and oral administration.

Siegall et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on columns 1-2).

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Siegall also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on columns 21-26).

Although the reference does not teach tumor-specific antigens per se, given the Malignancies set forth in Table 1 on columns 22-23, tumor-specific antigens would be inherent to the described tumors.

Also, note that B cells as well as dendritic cells, which express CD40, are antigen-presenting cells, which, in turn, would stimulate systemic immunity, including T cell immunity, when stimulated with agonistic anti-CD40 antibodies.

Although the reference is silent about the induction of "systemic T cell immunity against an antigen of the tumor", "wherein the treatment does not comprise immunization with an antigen of the tumor", "tumor-specific antigen" per se,

it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991).

Also, see M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have described a beneficial effect in another manner (e.g., induction of systemic T cell immunity) from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

8. New Grounds of Rejection.

Claims 13-21 and 25 are rejected under 35 U.S.C. § 102(e) as being anticipated Bedian et al. (U.S. Patent No. 7,338,660) (see entire document).

Bedian et al. teach methods of using agonistic / activating anti-CD40 antibodies (e.g., see column 10, paragraph 2; column 22, paragraph 3 - column 23, paragraph 6), which enhance CD40L-mediated interactions, including chimeric, humanized, Deimmunized antibodies (e.g., "such that the T and B cell epitopes have been eliminated") including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Human Anti-CD40 Antibodies and Characterization thereof, etc. on columns 15-37 and Examples on columns 48-90) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention, Detailed Description of the Invention, including Pharmaceutical Compositions and Kits on columns 38-43 and Claims). Here in Pharmaceutical Compositions and Kits, compositions and modes of administration via injection and oral administration (e.g., see columns 38-41).

Bedian et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see column 10, paragraph 2; Activation of CD40 by Anti-CD40 Antibody, Inhibition of Tumor Growth In Vivo by Anti-CD40 Antibodies, Induction of Apoptosis by Anti-CD40 Antibodies, Enhancement of Expression of Cell Surface Molecules, Enhancement of Secretion of Cellular Cytokines on columns 22-23).

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Bedian also teach the Pharmaceutical Compositions and Kits are drawn to a number of hyproliferative disorders such as lymphomas, leukemias, cancers sand carcinomas, such that hyperproliferative cells express CD40 or need not express CD40, including the use of the anti-CD40 antibodies to increase the immune response via the activation of antigen-presenting cells, T cells and cytokines (e.g., see column 10, paragraph 2 and columns 22-23).

Also, note that B cells as well as dendritic cells, which express CD40, are antigen-presenting cells, which, in turn, would stimulate systemic immunity, including T cell immunity, when stimulated with agonistic anti-CD40 antibodies.

Tumor-specific antigens and induction of systemic T cell immunity would be inherent to the treatment of the described hyperproliferative disorders via agonistic / activating anti-CD40 antibodies.

Although the reference is silent about the induction of "systemic T cell immunity against an antigen of the tumor", "wherein the treatment does not comprise immunization with an antigen of the tumor", "tumor-specific antigen" per se,

it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991).

Also, see M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have described a beneficial effect in another manner (e.g., induction of systemic T cell immunity) from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

9. Claims 13-25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Siegall et al. (US 2004/0235074 A1), Siegall et al. (U.S. Patent No. 6,843,989) AND Bedian et al. (U.S. Patent No. 7,338,660) in view of Melief et al. (WO 99/61065) (1449).

Applicant's arguments, filed 07/30/2008, have been fully considered but have not been found convincing essentially for the reasons of record.

Also, note the newly added teachings of Siegall et al. (U.S. Patent No. 6,843,989) and Bedian et al. herein.

Applicant argues the following.

The Examiner bears the initial burden of establishing a prima facie case of obviousness. If the Examiner does not satisfy this burden, then the Applicant is not obligated to submit evidence of non-obviousness. See MPEP §2142 at 2100-133 (8th ed., incorporating Revision No. 5, August 2006). The recently revised Examiner guidelines for assessing obviousness set forth detailed requirements based on asserted rationales for obviousness. The Rationales To Support Rejections Under 35 U.S.C. §103 provide the following possible rationales:

(A) Combining prior art elements according to known methods to yield predictable results;
(B) Simple substitution of one known element for another to obtain predictable results;
(C) Use of known technique to improve similar devices (methods, or products) in the same way;
(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
(E) "Obvious to try" choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and
(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See MPEP 8th Edition, rev. 6, §2141.

Applicant understands this rejection to conform to rationale G quoted above. The MPEP further sets forth the requirements for an obviousness rejection under this rationale:

To reject a claim based on [rationale G], Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. See MPEP 8th Edition, rev 6, §2143

The Office Action fails to cite any motivation for the combination of Siegall with Melief. The Office Action also fails to state why such a combination would hypothetically disclose the present invention.

As explained in detail above, Siegall does not contain an enabling disclosure of the present invention. Siegall does not teach to one of ordinary skill in the art the use of agonistic anti-CD40 antibodies for cancer treatment. Given the teachings of Siegall as outlined above, a person of skill in the art would determine that the use of the anti-CD40 antibody would not allow the induction of a systemic T cell response. Because the T cell response would not be induced, a skilled artisan would in fact be discouraged from using such an antibody. Melief does not cure the deficiencies of Siegall. Melief teaches that activation of anti-CD40 antibodies is insufficient to induce systemic T cell response, thus confirming the insufficiencies of Siegall. A combination of the two references teaches that induction of a T cell response requires both an activating anti-CD40 antibody and a CTL-activating peptide, thus teaching away from the present invention.

Further, the Examiner has agreed that the present invention is novel over Melief, thus admitting that Melief does not disclose the use of an anti-CD40 antibody without a CTL-activating peptide.

In addition, the present application teaches an effective method for treating tumors through the induction of a systemic T cell response. Siegall fails to recognize the importance of systemic T cell induction for tumor treatment.

In fact, Siegall teaches only the induction of an in vitro B cell response, as explained in detail previously. As outlined above,

Melief teaches the use of both a CTL-activating peptide and an anti-CD40 antibody. Thus, a person of skill in the art would have no motivation to use only an anti-CD40 antibody. The Examiner repeatedly admonished Applicants for concentrating "solely" on the Examples of Siegall (See Office Action page 5, third and fourth paragraph; page 7, eighth and ninth paragraph). However, Applicants respectfully submit that the Examiner appears to focus on a single paragraph of the Siegall specification in concluding that Melief discloses the use of an anti-CD40 antibody without the use of a CTL-activating peptide. It appears that the Examiner is ignoring the clear teaching of Melief in that Melief teaches the use of both a CTL-activating peptide and an anti-CD40 antibody. It appears that the Examiner is of the opinion that Melief does not contain a teaching away, but rather represents a skeptic view of a person of skill in the art in regards to the use of an anti-CD40 antibody as the sole agent in inducing systemic T cell immunity. However, the very case law cited by the Examiner indicates that "general skepticism" is relevant for assessing non-obviousness (see Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 726 (Fed. Cir. 1990); "General skepticism of those in the art--not amounting to teaching away--is also 'relevant and persuasive evidence' of nonobviousness?"; See Office Action at page 8). Thus, it appears that the Examiner is agreeing with Applicants in the conclusion that the combination of Siegall and Meliefteach away from the present invention.

Accordingly, for the reasons set forth above, it is respectfully requested that the rejection of claims 13-25 under 35 U.S.C. §103(a) be withdrawn as the combination of Siegall with Melief fails to render these claims obvious.

The arguments of counsel cannot take the place of evidence in the record.

See In re Schulze, 145 USPQ 716, 718 (CCPA 1965) and Meitzner v. Mindick, 193 USPQ 17, 22 (CCPA 1977).

Applicant's arguments and the examiner's rebuttal concerning the teachings of Siegall et al. (US 2004) are essentially the same as above and reiterated herein for applicant's convenience.

As pointed out previously, in contrast to applicant's assertions focusing on the induction of B cell proliferation and treatment in a SCID mouse model,

applicant ignores the clear teachings of Siegall et al. (US 2004) of treating cancer and immune disorders as well as activating/augmenting the immune response of a patient with agonistic anti-CD40 antibodies (e.g., see entire document, including Therapeutic Uses, Effective Doses, Formulations on pages 12-14 and Claims).

Also as pointed out previously, in contrast to applicant's focus on the Examples, Siegall et al. (US 2004) teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1) as pointed out previously.

Also, note that B cells as well as dendritic cells, which express CD40, are antigen-presenting cells, which, in turn, would stimulate systemic immunity, including T cell immunity, when stimulated with agonistic anti-CD40 antibodies.

Also as pointed out previously, as pointed out previously, Siegall et al. (US 2004) also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Applicant has not distinguished the prior art administration of an agonistic anti-CD40 antibodies that can activate/augment the immune response in the treatment of cancer from the claimed methods.

Applicant is reminded that the claimed method "does not comprise immunization with an antigen or the tumor" (e.g., see independent claim 13).

In contrast to applicant's assertions, treating tumors via "tumor-specific antigens" would be inherent in the prior art administration of an agonistic anti-CD40 antibodies that can activate / augment the immune response in the treatment of cancer, which includes the activation / augmentation of antigen-presenting cells as well including the teaching of the Malignancies set forth in Table 1 on pages 12-13 (Seigall et al. US 2004).

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have described a beneficial effect in another manner (e.g., induction of systemic T cell immunity) from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Also note the newly added teachings of Siegall et al. (U.S. Patent No. 6,843,989) has been added in a New Grounds of Rejection.

Applicant is reminded that U.S. patents are presumed valid by U.S. courts unless proven otherwise. See 35 U.S.C. 282.

Siegall et al. (U.S. Patent No. 6,843,989) teach methods of using agonistic anti-CD40 antibodies, which enhance CD40L-mediated interactions, including chimeric and humanized, including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Section 5.6 mAb S2C6 Antibody Derivatives on columns 14-16) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention and Section 5.9 Therapeutic Uses, Section 5.9.1 Effective Dose and Section 5.9.2 Formulations on columns 21-26 and Claims). Here in Section 5.9.2 Formulations, modes of administration via injection and oral administration.

Siegall et al. (U.S. Patent No. 6,843,989) teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on columns 1-2).

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Siegall et al. (U.S. Patent No. 6,843,989) also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40, including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on columns 21-26).

Although the reference does not teach tumor-specific antigens per se, given the Malignancies set forth in Table 1 on columns 22-23 (Siegall et al. U.S. Patent No. 6,843,989), tumor-specific antigens would be intrinsic or expected to the described tumors.

Also, note that B cells as well as dendritic cells, which express CD40, are antigen-presenting cells, which, in turn, would stimulate systemic immunity, including T cell immunity, when stimulated with agonistic anti-CD40 antibodies.

Although the reference is silent about the induction of "systemic T cell immunity against an antigen of the tumor", "wherein the treatment does not comprise immunization with an antigen of the tumor", "tumor-specific antigen" per se,

it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). "{i}t is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable". In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991).

Also, see M.P.E.P. 2145.

On this record, it is reasonable to conclude that the same patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that applicant may have described a beneficial effect in another manner (e.g., induction of systemic T cell immunity) from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Also, note the newly added teachings of Bedian herein.

Bedian et al. teach methods of using agonistic / activating anti-CD40 antibodies (e.g., see column 10, paragraph 2; column 22, paragraph 3 - column 23, paragraph 6), which enhance CD40L-mediated interactions, including chimeric, humanized, Deimmunized antibodies (e.g., "such that the T and B cell epitopes have been eliminated") including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Human Anti-CD40 Antibodies and Characterization thereof, etc. on columns 15-37 and Examples on columns 48-90) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention, Detailed Description of the Invention, including Pharmaceutical Compositions and Kits on columns 38-43 and Claims). Here in Pharmaceutical Compositions and Kits, compositions and modes of administration via injection and oral administration (e.g., see columns 38-41).

Bedian et al. teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see column 10, paragraph 2; Activation of CD40 by Anti-CD40 Antibody, Inhibition of Tumor Growth In Vivo by Anti-CD40 Antibodies, Induction of Apoptosis by Anti-CD40 Antibodies, Enhancement of Expression of Cell Surface Molecules, Enhancement of Secretion of Cellular Cytokines on columns 22-23).

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Bedian also teach the Pharmaceutical Compositions and Kits are drawn to a number of hyproliferative disorders such as lymphomas, leukemias, cancers sand carcinomas, such that hyperproliferative cells express CD40 or need not express CD40, including the use of the anti-CD40 antibodies to increase the immune response via the activation of antigen-presenting cells, T cells and cytokines (e.g., see column 10, paragraph 2 and columns 22-23).

Tumor-specific antigens and induction of systemic T cell immunity would be intrinsic or expected to the treatment of the described hyperproliferative disorders via agonistic / activating anti-CD40 antibodies.

Also, note that B cells as well as dendritic cells, which express CD40, are antigen-presenting cells, which, in turn, would stimulate systemic immunity, including T cell immunity, when stimulated with agonistic anti-CD40 antibodies.

Again in contrast to appellant's argument that Melief et al. teach away from the claimed invention, it is noted that a prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the appellant." See In re Haruna, 249 F.3d 1327, 58USPQ2d 1517 (Fed. Cir. 2001).

Also, in contrast to applicant's assertions; disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. See In re Susi USPQ 423 (CCPA 1971). A known or obvious composition does not patentable simply because it has been described as somewhat inferior to some other product for the same use. See In re Gurley 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See MPEP 2123.

General skepticism of those in the art -- not amounting to teaching away -- is also "relevant and persuasive evidence" of nonobviousness. Gillette Co. v. S.C. Johnson & Son, Inc. , 919 F.2d 720, 726, 16 USPQ2d 1923, 1929 (Fed. Cir. 1990). In effect, "teaching away" is a more pointed and probative form of skepticism expressed in the prior art. In any case, the presence of either of these indicia gives insight into the question of obviousness.

Also, with respect to applicant's assertions of lack of motivation and particularly Rationale G, applicant is reminded that the prior art references must be considered in their entirety.

Given the examination guidelines for determining obviousness under 35 U.S.C. 103 in view of the Supreme Court decision in KSR International Co. v. Teleflex Inc. 82 USPQ2d 1385 (2007) and the Examination Guidelines set forth in the Federal Register (Vol. 72, No. 195, October 10, 2007) and incorporated recently into the MPEP (Revision 6, September 2007),
the following rationales to support rejection under 35 U.S.C. 103(a) are noted:

Combining prior art elements according to known methods to yield predictable results.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g, agonistic / activating anti-CD40 antibodies) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (administering said agonistic / activating anti-CD40 antibodies to treat cancer, including the activation of the immune system) with no change in their respective functions and the combination would have yielded nothing more than predictable results of treating cancer with agonistic anti-CD40 antibodies in the absence of administering tumor antigen.

Applying a known technique to a known product ready for improvement to yield predictable results.

The rationale to support a conclusion that the claims would have been obvious is that a particular known technique (administering agonistic / activating anti-CD40 antibodies to treat cancer and to boost host immune responses via antigen presenting cells and cytokines) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known product (e.g. agonistic /activating anti-CD40 antibodies) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

"Obvious to try" --- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success.

The rationale to support a conclusion that the claim would have been obvious is that a person of ordinary skill has good reason to pursue the known options (e.g. administration of agoniistic / activating anti-CD40 antibodies to treat cancer and to boost immune response) within his or her technical grasp. This leads to the anticipated success of treating cancer with agonistic / activating anti-CD40 antibodies in the absence of tumor antigens. It is likely the product not of innovation but of ordinary skill and common sense.

Some teachings, suggestion, or motivation in the prior art that would have lead one of ordinary skill to modify the prior art reference to arrive at the claimed invention.

Since treating cancer and boosting immune responses with agonistic / activating anti-CD40 antibodies would have been predictable at the time of the invention, there would have been reasonable expectation of successful development of an treating cancer with agonistic / activating anti-CD40 antibodies in the absence of the administration of tumor antigen as claimed. The prior art had recognized the obstacles of treating cancer with agonistic antibodies that boost the immune systems and had suggested and relied upon the administration of agonistic / activating anti-CD40 antibodies to treat cancer and to boost immune responses via antigen-presenting cells and the elaboration of cytokines that affect various immune responses, including T cell immune responses, to accomplish this goal. The claims were obvious because it would have been obvious to try the known agonistic / activating anti-CD40 antibodies to treat cancer in the absenee of administering tumor antigen with a reasonable expectation of success.

Again, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the combination of the prior art disclosure in motivating the ordinary artisan to administer anti-CD40 antibodies to patients with tumors.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to treat patients with tumors with agents that could enhance the immune system or that could treat tumors,
incorporating agonistic / activating anti-CD40 antibodies in therapeutic regimens with tumor-bearing patients would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such methods to effectively treat tumors in a subject.

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Siegall et al. (US 2004) teach methods of using agonistic anti-CD40 antibodies, which enhance CD40L-mediated interactions, including chimeric and humanized, including antigen-binding fragments encompassed by the claimed invention (e.g., see Detailed Description of the Invention and Examples, including Section 5.6 mAb S2C6 Antibody Derivatives in paragraphs [0081] – [0091]) in order to augment immune responses or the immune system for the treatment of cancer (e.g., see Background of the Invention, Summary of the Invention and Section 5.9 Therapeutic Uses, Section 5.9.1 Effective Dose and Section 5.9.2 Formulations on pages 12-14 and Claims). Here in Section 5.9.2 Formulations, modes of administration via injection and oral administration.

Siegall et al. (US 2004) teach that CD40:CD40L interactions are involved in immune responses and interactions, including dendritic cells (e.g., see Section 2.1 CD40 and CD40 Ligand on page 1)

It is noted that the claims required that "the treatment does not comprise immunization with an antigen of the tumor".

Siegall et al. (US 2004) also teach the Therapeutic Uses of said antibodies for the treatment or prevention of malignancies (including but not limited to carcinoma and hematologic malignancies), wherein the malignant cells express CD40 or need not express CD40,
including its use to increase the immune response of an immunosuppressed individual, such as a person suffering from malignancy via the promoting the proliferation and/or differentiation of CD40-bearing cells as a means of directly treating malignancy or as an adjunct to chemotherapy (e.g., see Therapeutic Uses on pages 12-13).

Although the reference does not teach tumor-specific antigens per se, given the Malignancies set forth in Table 1 on pages 12-13 (Siegall et al. US 2004), tumor-specific antigens would be inherent to the described tumors.

In addition, Melief et al. teach that CD40 ligation can provide an already protective tumor-specific vaccine with the capacity to induce therapeutic CTL immunity in tumor bearing individuals (e.g., see page 5, paragraph 2);
the prior art teaches the induction of T cell immunity to tumor specific antigen wherein the treatment does not comprise immunization with an antigen of the tumor,
since the individual has already been treated with a tumor specific antigen vaccine and the treatment does not require further immunization with the tumor specific antigen.
the treatment for tumor specific antigens,

Siegall et al. (US 2004) does not teach the known applicability of using DEIMMUNISED and human antibodies as therapeutic antibodies at the time the invention was made.

Melief et al. teach methods of using dendritic cell activating anti-CD40 antibodies, including chimeric, DEIMMUNISED, humanized and human antibodies, including antigen-binding fragments encompassed by the claimed invention (e.g., see pages 4 and 9-12 and Claims) for the treatment of cancer (e.g., see Summary of the Invention on pages 4-5 and Claims). The Background of the Invention and Summary of the Invention teach the use of such anti-CD40 antibodies to activate dendritic cells and CTLs to act against tumor cells and cancer.

Although Siegall et al. (US 2004) does not teach administering the anti-CD40 antibodies intra-tumorally, Melief et al. teach administration directly to the tumor in addition to the known and conventional modes of administration via injection and oral administration or (e.g., see page 12, paragraph 2 and Claims, including Claim 7 of Melief et al.).

Melief et al. teach the stimulation via CD40:CD40L, wherein the CD40L was the known receptor for CD40 at the time the invention was made (e.g., see Background of the Invention and Summary of the Invention).

Given the teaching that CD40 ligation can provide an already protective tumor-specific vaccine with the capacity to induce therapeutic CTL immunity in tumor bearing individuals (e.g., see page 5, paragraph 2);
the prior art teaches the induction of T cell immunity to tumor specific antigen wherein the treatment does not comprise immunization with an antigen of the tumor,
since the individual has already been treated with a tumor specific antigen vaccine and the treatment does not require further immunization with the tumor specific antigen.

Also, it is noted that methods of administration encompass a result effective variable. It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs, Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious). As the claimed methods of administration were known to the ordinary artisan, it would have been obvious to optimize both the mode of administration as well as dosage amounts.

Depending on the needs of the patient and the nature of the therapeutic endpoint, one of ordinary skill in the art at the time the invention was made would have been motivated to provide antagonistic antibodies via multiple modes of administration, including the intravenous, subcutaneous and intramuscular routes of administration as known and practiced at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments have not been found persuasive.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

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